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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,056	12/19/2001	Karen Reue	407T-898010US	2961

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EXAMINER
WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 05/07/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/028,056	REUE et al.
Examiner	**Art Unit**
Cynthia B Wilder	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 2, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-63* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25, drawn to a method of screening for agent, classified in class 435, subclass 6 and 7.1.

II. Claims 26-29, drawn to an isolated nucleic acid, classified in class 536, subclass 23.1.

III. Claims 30-32, drawn to Antibody, classified in class 424, subclass 130.1.

IV. Claims 33-35, drawn to isolated polypeptide, classified in class 530, subclass 350.

V. Claims 36-40, drawn to a transgenic animal, classified in class 800, subclass 8.

VI. Claims 41-53, drawn to a method of identifying a predilection to a disease, classified in class 435, subclass 6 and 7.1.

VII. Claims 54-61, drawn to a method of mitigating symptoms to disease, classified in class 514, subclass 44.

VIII. Claims 62-63, drawn to a method of inhibiting fat accumulation, classified in class 435, subclass 173.6.

2. Inventions I, VI, VII, VIII and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for

using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid of invention II can be used in a materially different process besides in the method as disclosed in Inventions I, VI, VII and VIII. The method can be used in methods of mutagenesis or in methods of differential display to detect expression of a target of interest or in methods of mini-sequencing or in SSCP (single strand conformational polymorphism) or in ligase-mediated amplification to detect a mutation of interest. Alternatively, the nucleic acid can be used in genomic mapping or fingerprinting analysis.

3. Inventions I, VI, VII, VIII and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody of invention III can be used in a materially different process besides in the methods of Inventions I, VI, VII, VIII. The antibody can be used in immunoassays or immunoprecipitation methodologies to detect a specific target protein, e.g., IL receptor.

4. Inventions I, VI, VII, VIII and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide can be used in methods of mutagenesis or in two-hybrid systems or in receptor/ligand binding studies.

5. Inventions I, VI, VII, VIII and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the transgenic animal of invention V can be used in other animal model systems and research studies besides those previously recited.

6. Inventions I, VI, VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operations leading to different effects. for example, invention I is drawn to a method of screening an agent which operates by using a hybridization or binding assay to detect a test agent whereas invention VI is drawn to a method of identifying a predilection to a disease, e.g., diabetes, which operates by determining activity of a LPIN1 gene or gene product from a diseased organism or as compared to the activity of the LPIN1 gene or

gene product of a healthy organisms. Invention VII is drawn to a method of mitigating symptoms of a disease which operates by treating with an agent with modulates the activity of a LPIN1 gene product whereas Invention VIII is drawn to method of inhibiting fact accumulation in a mammal which operates by transfecting an organism with a nucleic acid that inactivates the lipin gene. The different methods are patentably distinct requiring different fields of search.

7. Inventions II, III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function, structure and effected. For example, the method of invention II is drawn to an isolated nucleic acid which is composed of nucleotides and functions in methods of hybridization and amplification whereas invention III is drawn to an antibody which is composed of amino acids linked by peptide bonds. Antibodies are glycosylated and their tertiary structure is unique, where four subunits associated via disulfide bonds form into a Y-shaped symmetric dimer. The antibodies function in immunoassays. The polypeptide is composed of amino acids linked by peptide bonds and arrange in a complex combination of alpha helices, beta pleated sheets, hydrophobic and hydrophilic domains. The polypeptide can function as fusion proteins with enzymatic functions. The transgenic animal is a complex organism that is employed in e.g., animal research methods and models. Such organisms cannot be employed as e.g., probes or primers, a peptide and they differ in both structure and function from the nucleic acids, antibodies and polypeptides.

8. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

9. This application contains claims directed to the following patentably distinct species of the claimed invention:

(a) Claims 1-25 are generic to nucleic acids (claims 1-7, 10, 12, 13, 16, 18, 19, 22-25), polypeptides (claims 1, 2, 8-15, 17, 20-25), and test agents, e.g., antibody, protein, nucleic acid, small molecule (claims 14-17).

(b) Claims 26-28 are generic to human lipin 1A, mouse lipin 1A or mouse lipin 1B

(c) Claims 41-53 are generic to nucleic acids (claims 41-43, 46-51), and polypeptides (claims 41, 44-46, 52, 53).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to be examined if any one of Groups I, II or VI is elected.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of

an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

13. ***Contact Information***

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Group's receptionist at (703) 308-0196.

cbw
May 2, 2003

Cynthia B. Wilder, Ph.D.
Patent Examiner
Art Unit 1637